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Proposed Maximum Residue Limit PMRL2015-14

Sedaxane

(publié aussi en français)

12 May 2015

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2015-14E (print version)
H113-24/2015-14E-PDF (PDF version)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on various commodities to the product label of Helix Vibrance, containing technical grade thiamethoxam, difenoconazole, metalaxyl-M (and S-isomer), fludioxonil and sedaxane, is acceptable. The specific uses approved in Canada are detailed on the label of Helix Vibrance, *Pest Control Products Act* Registration Number 31454.

The evaluation of this sedaxane application indicated that the end-use product has merit and value, and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for sedaxane is being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRLs can be found in Appendix I. Existing MRLs for thiamethoxam, difenoconazole, metalaxyl and fludioxonil on mustard seeds are adequate to cover this use on the Helix Vibrance label.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for sedaxane, is as follows.

Table 1 Proposed Maximum Residue Limits for Sedaxane

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Sedaxane	*N*-[2-[1,1'-bicyclopropyl]-2-ylphenyl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	0.01	Mustard seeds (condiment type)

[1] ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. Currently, there are no American tolerances for sedaxane on mustard seeds (condiment type) as listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. Currently, there are no Codex MRLs[1] listed for sedaxane in or on mustard seeds (condiment type) on the Codex Alimentarius Pesticide Residues in Food webpage.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (Where Different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Mustard seeds (condiment type)	0.01	Not established.	Not established.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for sedaxane up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that they are entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Field Trial Data Used to Support the Proposed Maximum Residue Limit

No new residue data for sedaxane were submitted to support the uses on the Helix Vibrance label. Previously reviewed residue data from field trials conducted in/on canola were reassessed in the framework of this petition.

Maximum Residue Limits

The recommendation for a maximum residue limit (MRL) for sedaxane was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for mustard seeds (condiment type).

Table A1 Summary of Field Trial and Processing Data Used to Support Maximum Residue Limits

Commodity	Application Method/Total Application Rate (g a.i./100 kg seed)[1]	Days After Planting (days)	Maximum Residues (ppm)	Minimum Residues (ppm)	Experimental Processing Factor
Canola seed[2]	Seed treatment/ 5.9-7.5	84-232	< 0.01	< 0.01	Could not be determined as residues were not quantified in the seed and processed commodities.

[1] g a.i./100 kg seed = grams of active ingredient per 100 kilograms of seed.
[2] The proposed MRL on mustard seeds (condiment type) is based on canola residue data.

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of sedaxane. Residues of sedaxane in this commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.